Acceptability and feasibility of a Japanese Version of STrAtegies for RelaTives (START-J): A manualized coping strategy program for family caregivers of relatives living with dementia

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Acknowledgements

We would like to extend our appreciation to the participants and all staff in the psychiatric outpatient service at Nippon Medical School Hospital and Musashi Kosugi Hospital Dementia Center. We would also like to thank M. Araki, who is a clinical psychologist, for her assistance with assessments and interventions.

Funding

This study was supported by JSPS KAKENHI Grant Numbers JP26590165, JP18K13356 and the 26th Pfizer Health Research Foundation.

Declaration of Competing Interests

The authors declare that there is no conflict of interest.

Abstract

The rising older population in Japan is associated with a rise in cases of dementia. Support for the increased number of family caregivers of people living with dementia is crucial, as caring may negatively affect a family caregiver's health. This study seeks to evaluate the feasibility and applicability of a recently developed Japanese version of START (STrAtegies for RelaTives). START is a psychosocial coping intervention program developed in the United Kingdom that has been shown to improve caregivers' mood and quality of life (QOL) in a randomized controlled trial. We made changes to START (e.g., idioms, linguistic nuance, and providing care insurance information suited for Japan) to make it culturally appropriate. Fourteen Japanese female family caregivers of relatives with mild dementia (n=10) or mild cognitive impairment (n=4) were referred to the study, but six were excluded owing to illness and busyness. This single-arm study had a before-after trial evaluating psychological outcomes including depression, anxiety, QOL, and subjective care burden. The acceptance retention and satisfaction rate suggest the feasibility and acceptability of the START program; 8/14 (>55%) eligible, prospective participants consented and were included in this study, all

(8/8) of whom completed all START sessions. The mean program satisfaction score was 30.25 (SD = 2.25) out of a potential 32. The results suggest that it is feasible and acceptable to deliver START in Japanese and based on the results of analysis using a linear mixed model, there is initial indication that the intervention improved family caregivers’ QOL, depressive symptoms, and care burden.

Keywords: START, dementia, family caregiver, care burden, psychoeducation

List of Abbreviations

CBT – Cognitive Behavioral Therapy

CSQ-8 – Client Satisfaction Questionnaire

CWC – Coping With Caregiving

HADS – Hospital Anxiety and Depression Scale

HADS-A – Hospital Anxiety and Depression Scale-Anxiety

HADS-D – Hospital Anxiety and Depression Scale-Depression

J-ZBI_8 – Zarit Caregiver Burden Interview-the short version

MCI – Mild Cognitive Impairment

MINI – Mini-International Neuropsychiatric Interview

MMSE – Mini-Mental State Examination

NPI-B – Neuropsychiatric Inventory-Caregiver’s Burden

NPI-Q – Neuropsychiatric Inventory Questionnaire

PHQ-9 – Patient Health Questionnaire

QOL – Quality of Life

RCT – Randomized Controlled Trial

SF8 – Short Form 8 Health Survey

SF8-MCS – Short Form 8 Health Survey-Mental Component Summary

SF8-PCS – Short Form 8 Health Survey-Physical Component Summary

SF36 – Short Form Health Survey

START – StrAtegies for RelaTives

Background

The World Alzheimer Report 2015 reported that 46.8 million people worldwide are currently living with dementia, including 22.9 million in Asian countries with a crude estimated prevalence of 4.7% (Prince et al., 2015). The number of people with dementia in Japan has been increasing as the population ages; it is predicted that the number of people living with this condition will reach 7 million in 2025 (Ninomiya, Kiyohara, Ohara, & Yonemoto, 2015), with one in five older people in Japan living with dementia. There are, therefore, more family caregivers caring for relatives living with dementia, and they experience a high level of depressive symptoms and low quality of life (QOL) (Takai et al., 2009). This is in line with international studies that show that family caregivers commonly experience psychological distress such as anxiety and depression (Mahoney, Regan, Katona, & Livingston, 2005) and that these, in addition to an increase in distress and burden, are related to family members' having higher levels of neuropsychiatric symptoms of dementia, which are related to a decrease in caregivers' psychological well-being (Pinquart & Sörensen, 2003). Moreover, a third of family caregivers have reported acting abusively (Cooper, Selwood, & Livingston,

2008) and this abusive behavior by family caregivers increased over time and that such behavior was predicted by anxiety and depression (Cooper, Blanchard, Selwood, Walker, & Livingston, 2010).

The Japanese Health, Labour and Welfare Ministry adopted a plan to strengthen support for older people living with dementia and their families in 2015 (Ministry of Health, Labour and Welfare, 2016); the plan entails a comprehensive initiative to accelerate measures for the support of people living with dementia. The basic concept is to establish a society where people living with dementia can lead a life of dignity in comfortable and familiar surroundings for as long as possible. The plan is not only to raise public awareness and promote understanding of dementia, but also to support people living with dementia and their caregivers in an effort to prioritize both their standard of living with dementia and that of their families. However, there is currently little support available for caregivers in Japan. Any existing support has centered on family support groups and dementia cafes. These interventions have not been evaluated in Japan therefore their effectiveness remains uncertain. Therefore, clinical studies on helping family caregivers in Japan are essential.

In some countries, effective psychosocial interventions for family caregivers of relatives living with dementia have been developed, but overall, most evidence for interventions for caregivers has shown that they are not effective (Patnode et al., 2019). Two psychoeducational groups called Coping With Caregiving (CWC; Gallagher-Thompson et al., 2003) and Project CARE (Gonyea, O’Connor, & Boyle, 2006), aimed at alleviating caregivers’ psychological distress and care burden, are based on the principles of a cognitive behavioral approach. These group-format interventions can facilitate mutual support provision among participating caregivers and can be cost-effective. However, these interventions cannot address complex problems resulting from the diverse needs of individual families (Spijker et al., 2008).

Group-format psychosocial intervention programs include peer support (Laakkonen et al., 2016) and some have evaluated cost-effectiveness (Hopkinson, Reavell, Lane, & Mallikarjun, 2018), as well as overall efficacy (Dickinson et al., 2017). However, a group format makes it difficult to address the personalized needs of caregivers. Moreover, some caregivers might not be able to discuss their concerns as openly in this format due to stigma in the Japanese context.

Although the Japanese government has been engaging in educational activities on dementia and considering support for people living with dementia and their caregivers, stigma about dementia among people in Japan remains commonplace (Aihara, Kato, Sugiyama, Ishi, & Goto, 2016). Therefore, family caregivers may be reluctant to share their relative's diagnosis of dementia or to discuss their experiences of dementia. Thus, an individualized program may prove a good fit for Japanese family caregivers.

In the United Kingdom (UK), an effective psychosocial program for family caregivers of relatives living with dementia called START (STrAtegies for RelaTives) has been developed. This program, which draws from CWC, is individualized and requires active participation. In a randomized control trial, the program reduced caregivers' anxiety and depression, improved their QOL, and was cost-effective (Knapp et al., 2013; Livingston et al., 2013), and these effects were sustained two and six years after the intervention (Livingston et al., 2014; Livingston et al., n.d.). Individualized therapies for caregivers seem to be the most effective in delaying the admission of care recipients to a care facility and are more efficacious than group interventions in reducing caregivers' morbidity (Selwood, Johnston, Katona, Lyketsos, & Livingston, 2007; Spijker et al., 2008). Although the original START study did not include it, mild cognitive impairment (MCI) is also associated with neurobehavioral symptoms and memory problems, and caregivers of relatives with MCI also experience a burden of care (Hayashi et al., 2013). Therefore, family caregivers of those with MCI could also benefit from interventions.

Before this study, we administered the Japanese version of START (START-J) to a Japanese family caregiver whose mother was diagnosed with dementia in a single case study. The results suggested that the program reduced the caregiver’s care burden and depressive and anxious symptoms and improved her QOL (Kashimura, Nomura, Ishiwata, & Kitamura, 2018). However, this was only a single case report. Thus, in the present study, we aimed:

1. to test the feasibility and acceptability of START-J with many caregivers whose relatives were diagnosed with either dementia or MCI in START-J.

We defined this as 1) >50% of referrals would be recruited into the study, 2) the follow-up rate would be >80%, 3) attendance would be >5 sessions as adherence, based on a previous feasibility study (Livingston et al., 2018), and 4) the participants had a positive opinion of the intervention.

2. that intervention could be delivered with fidelity.
3. that we would be able to collect outcome measures and that these would show outcomes in line with the START efficacy RCT for mood and QOL.

Methods

Participants

We recruited family caregivers who were all Japanese and had relatives with a diagnosis of dementia or MCI. The inclusion criteria for participation in this study were: 1) caring for relatives living with dementia or MCI and staying with them for >3 days a week for a total of >10 hours a week; 2) being aged 20-90 years; 3) experiencing care burden and any somatic or mental complaints; 4) having had a conflict-ridden relationship with a relative who needed care and a desire to improve it; 5) being able to participate in more than two-thirds of the program; 6) being able to perform homework at home for >30 minutes every day; 7) residing within visiting distance of the hospital; and 8) speaking Japanese. The exclusion criteria were: 1) having any severe, life-threatening physical condition or a severe mental disorder such as schizophrenia, bipolar disorder, substance-related disorder, or a Cluster A personality disorder; 2) having been given less than a year to live due to any diseases such as cancer; 3) indicating an inability to continue participating in the study due to other commitments, lack of motivation, dyslexia, difficulty with comprehension of the program, or severe cognitive decline before commencement of the program; 4) hospitalization due to severe depression or anxiety, self-injury, or suicide attempts; and 5) having already participated in another structured psychological therapy. These criteria differed from the original START study, which was a pragmatic trial including any family caregiver who was in the geographic area (Livingston et al., 2013). However, we decided to set these more detailed criteria, as this study was the first trial of START-J and we thus desired to conduct it with the utmost care and caution.

Setting and Procedure

This study was a single-arm pre/post design (Figure 1). We conducted the trial with family caregivers at a psychiatric outpatient department of XXX Medical School Hospital (the monthly average number of outpatients in the psychiatric department of the hospital was approximately 2,300; of these, the proportion of patients with dementia or MCI was 3.69%), without their care-receiving relatives with dementia or MCI being present. Typically, family caregivers can receive the START sessions at a place of their choosing (usually their own homes) (Livingston et al., 2013), but outreach psychology services were not yet available in Japan, so we conducted the program at an outpatient service. Doctors (i.e., psychiatrists and neurologists) of the relatives with MCI or dementia referred the family caregivers.

Ethical Approval

The Ethics Committee of Nippon Medical School Hospital approved this study (27-01-543), and the participants gave written, informed consent for participation and this publication prior to commencement of the program. The study procedures were conducted in accordance with ethical standards as per the Declaration of Helsinki (as revised in Brazil, 2013; World Medical Association, 2013).

The study team approached the participants who showed initial interest in the study and provided them with information on the study (e.g., its purpose, program content, potential benefits of participating, duration, and time commitment per month). At this point, those eligible and wanting to participate gave written informed consent (N=8).

[Insert Figure 1.]

Those agreeing to participate in this study were referred to a psychologist who was part of the assessment staff and subsequently completed baseline assessment before conducting START-J. Participation in this trial was provided at no cost because it was for research purposes. In addition, round-trip transportation allowances for each session and rewards (3,000 yen) for each assessment (total 3 times; pre, post, 6-month follow-up) were provided to participants. This was explained to them before their informed consent was obtained.

Intervention

START is an individualized and manualized coping program aimed at improving the mental health of family caregivers of relatives living with dementia. The

START manual (Livingston et al., 2013) was translated after obtaining permission from the original authors (Kashimura et al., 2018). We translated the START manual from English to Japanese using an interactive consensus process (Douglas & Craig, 2007), that is, a parallel translation approach. Independent translators who were native Japanese speakers, able to speak and read English, and clinical psychologists, psychiatrists, or neurologists who specialized in geriatrics performed their own translation of the same manual. After completing each translation, two committee meetings were held to obtain a consensus for the final translated version of the START-J manual. Generally, the linguistic and cultural context between different languages and countries should be considered in the translation process; however, this manual was very familiar to the Japanese translators because START is informed by cognitive behavioral therapy (CBT), which is commonly used in Japan. In addition, almost all explanations, descriptions, and case examples shown in the original START manual were deemed to fit. However, Session 6 focuses on providing information about future care options and available services to support older people and there are differences in the health insurance systems between the UK and Japan. After receiving approval from the original author, we modified this session accordingly.

As in the original program, START-J consisted of eight sessions (Table 1). The program involves several interventions, such as psychoeducation, behavioral analysis, cognitive restructuring, communication skills, and behavioral activation. Additionally, there are seven types of relaxation training, including breathing, imagery technique, and stretching to relieve stress at the end of each session. We set 60 to 90 minutes for each session based on the time the sessions in the initial study took Livingston et al.'s (2013) and adapted each session time in response to the need of participants in that specific circumstance. START does not need to be delivered by clinical psychologists, although it was necessary for professionals who were knowledgeable about START to train the individuals who conducted the program. In the original START RCT (Livingston et al., 2013), non-clinically trained staff delivered the program with good levels of effectiveness and intervention fidelity.

[Insert Table 1.]

The program was delivered by two Japanese clinical psychologists with more than five years of training; one of the two was familiar with CBT. One of the therapists participated in all the translation processes of the START manual and was sufficiently familiar with the manual. Before this trial, we devised a fidelity check sheet in Japanese comprising the most important components of each session, which was based on the original START research (Livingston et al., 2013). In order to measure fidelity, the therapists recorded each session with each participant, and research members who were not involved in the session rated the fidelity of the sheet relative to the manual. We set six questions on each fidelity sheet; “all information covered,” “the caregiver successfully completed the task in the manual,” “successfully encouraging caregiver to think of the material,” “successfully teach relaxation,” “successfully introduced the homework,” and “keeping the caregiver focused on the manual.” The study team evaluated each question with scores ranged from 1 (not at all) to 5 (very well) and overall fidelity scores ranged from 6 (the lowest) to 30 (the highest). If the scores were low, the research members (clinical psychologists and psychiatrists) discussed the reasons and solutions for the upcoming sessions during our peer supervision. The therapists administering the program, plus another clinical psychologist who did not conduct the program, trained >10 hours peer-to-peer on the intervention protocol and held regular peer supervision for ongoing cases.

Assessment

A well-trained study member who did not deliver START assessed the participants, excluding the self-reported scales below, which they filled out by themselves. Participants were interviewed three times for the assessment: at baseline (pre-intervention), immediately after the program (post-intervention), and at follow-up (in six months) in the hospital. We collected the socio-demographic details of participants and their care-receiving relatives, such as age, sex, relationship with the care recipient, the care recipient's diagnosis, level of education (year), job history, and living conditions at baseline.

The Mini-International Neuropsychiatric Interview (MINI)

The MINI (DSM-IV; ICD-10; Sheehan et al., 1998) is a brief structured interview that was used at the baseline assessment to evaluate the participants for the exclusion and inclusion criteria.

The Mini-Mental State Examination (MMSE)

The MMSE, which measures cognitive functioning (Folstein, Folstein, & McHugh, 1975; Mori, Mitani, & Yamadori, 1985), was used at the baseline assessment to evaluate the participants for the exclusion criteria.

The Client Satisfaction Questionnaire (CSQ-8)

We administered the CSQ-8, which is an eight-item (quality of service, kind of service, whether needs were met, recommend to a friend, amount of help, deal with problems, overall satisfaction, and return needed) self-report scale (rated on a 4-point scale with scores ranging from 8 to 32, with higher scores indicating greater satisfaction) measuring participants' satisfaction (Bowling, 1995; Tachimori & Ito, 1999) to participants after receiving START-J.

The Patient Health Questionnaire-9 (PHQ-9)

The PHQ-9 is a nine-item self-report questionnaire rated on a 4-point scale measuring depressive symptoms (Spitzer, Kroenke, & Williams, 1999; Muramatsu et al., 2007). This validated scale (Kroenke & Spitzer, 2002; Martin, Rief, Klaiberg, & Braehler, 2006) was used at the pre- and post-assessments.

The Hospital Anxiety and Depression Scale-Anxiety only (HADS-A)

The HADS is a 14-item self-report scale rated on a 4-point scale that measures anxiety and depression (Kitamura, 1993; Zigmond & Snaith, 1983). This validated scale (Bjelland, Dahl, Haug, & Neckelmann, 2002; Herrmann, 1997) has two subscales: anxiety (HADS-A) and depression (HADS-D). We only used the HADS-A at the pre- and post-assessments, as the Japanese version of the HADS-D has a poor psychometric property (Hatta et al., 1998).

The Japanese version of the Zarit Caregiver Burden Interview-the short version (J-ZBI_8)

The J-ZBI_8 (Arai, Tamiya, & Yano, 2003) is an eight-item self-report instrument measuring subjective care burden. This is the shortened version of the Zarit Caregiver Burden Interview (Zarit, Reever, & Bach-Peterson, 1980; Zarit & Zarit, 1990) and was used at the pre- and post-assessments in this study.

The Short Form 8 Health Survey questionnaire (SF8)

The SF8 is a self-report scale assessing eight dimensions of generic health (Fukuhara & Suzukamo, 2004). The SF8 scores are analyzed in terms of two summary scores, Physical Component Summary (SF8-PCS) and Mental Component Summary (SF8-MCS), which were used at the pre- and post-assessments.

The Neuropsychiatric Inventory Questionnaire (NPI-Q)

The NPI-Q is a 12-item brief version of the NPI (Cummings et al., 1994); it is a caregiver-informant scale, intended for self-administration, rating the severity of neuropsychiatric symptoms (NPI-Q) on a scale from 0 to 3 and the caregiver's burden (NPI-B) on a scale from 0 to 5 (Kaufer et al., 2000; Matsumoto et al., 2006). This tool was used at the pre- and post-assessments.

Statistical analysis

In addition to examining the feasibility and acceptability of the scale, we calculated descriptive statistics for all of the outcome variables, and a linear mixed model was adopted for the comparison of the outcome scores evaluating the impact of START-J. In a linear mixed model, time as a fixed factor and participant as a random factor were included. Further, we used the restricted maximum likelihood method and Cohen's *d* to calculate the effect size to indicate whether results were in line with the original trial. The study was not powered for significance. All statistical analyses were carried out using IBM SPSS Statistics, version 22.

Results

Recruitment / retention / intervention adherence and delivery

Fourteen participants (2 males and 12 females, mean age 66.77±12.50) were referred from one site (a psychiatric outpatient department of XXX Medical School Hospital) between April 1, 2015 and December 25, 2016. However, six people declined to participate because they were too busy (N=2; one male and one female), were in poor health condition (N=2; two females), were not interested (N=1; one male), or did not wish to take part (N=1; one female). Eight out of 14 (57%) participants consented to participating in this study, and all sessions were delivered to all participants (8/8=100%) without the relative with dementia or MCI present. On average, each session took 68.88±6.74 min. There were no adverse events during the trial. The fidelity score was rated for each session for all eight participants (for a total of 64 sessions), and the average score was 25.48±2.38 (30 is the highest possible score). All participants remained in the study at post-intervention follow-up (8/8; 100%), with one participant dropping out before the six-month follow-up (7/8; 88%). Table 2 shows the participants' demographic data. We delivered the program to eight women and thereafter analyzed their data. None of the participants had any physical conditions or psychiatric disorders as assessed by the MINI, and none showed any cognitive decline as evaluated by the MMSE (all participants' MMSE score = 30).

[Insert Table 2.]

Program satisfaction

We tested participants' satisfaction with START-J using the CSQ-8. The mean score was 30.25 (SD = 2.25), ranging from 25 to 32. Table 3 shows that each item of the CSQ-8 had a sufficiently high score concerning program satisfaction-looks as if most scores were very high. The mean score of Item 6 is the lowest of the items.

[Insert Table 3.]

Changes in outcomes at three time points

All outcome changes over the study period (pre-assessment, post-assessment, and 6-month follow-up) are shown in Table 4. We used a mixed-effect regression model with time as a fixed effect and participant as a random effect for comparison with each score. The effect of time was significant for the PHQ-9, J-ZBI_8, and SF8-MCS, while results for the HADS-A, SF8-PCS, NPI-Q, and NPI-B were not significant. The effect sizes as demonstrated by Cohen’s *d* for each significant outcome at post-assessment and 6-month follow-up, respectively, were as follows: PHQ-9: 1.33 and 1.26; J-ZBI_8: 1.59 and 1.54; SF8-MCS: 1.14 and 1.35.

[Insert Table 4.]

Discussion

Main findings

As we hypothesized, we invited 14 candidates and, of those, over 50% of family caregivers consented to participate in START-J. In addition, we had 100% retention between baseline and initial follow-up and over 80% of those were followed up at 6 months. All participants completed every session, and there were no adverse events throughout the trial. Moreover, the fidelity scores were high which shows it can be delivered as intended. The criteria for feasibility and acceptability were based on a similar feasibility study by Livingston et al. (2018), and these criteria are standard for evaluation.

In terms of the delivery of START-J, each session took approximately 60 minutes on average as with the original START (Livingston et al., 2013). The required time for each session of START-J is similar to the time typically required for general counseling.

Regarding program satisfaction, the participants' scores on the CSQ-8 were high. In terms of each item, almost all domains that were measured by the CSQ-8 were high. The participants would recommend the service to a friend, which suggests reduced stigma and secrecy, and that they were very satisfied overall. However, item 6 ("the service received helped to deal with problems") was high but slightly lower than others although participants rated "needs met" very highly. START-J includes some useful skills, such as psychoeducation and behavioral analysis for understanding relatives with dementia or MCI. Other skills such as cognitive reconstruction and behavioral activation are aimed toward improving the caregiver's stress management, rather than dealing directly with their relatives. This may mean that this program leaves something to be desired for caregivers focused on how to control or influence their relatives. Clarifying the cause of the score difference will require a qualitative investigation utilizing interviews in the future. Moreover, regarding the fidelity of START-J, the fidelity score relative to the manual was high. Of course, it may also be considered moderate because the research team members carefully discussed each session during our peer supervision. We believe that the situation/events would be different with daily support services, such as a community setting; thus, the fidelity result must be interpreted carefully. Based on these results, START-J can be considered to have sufficient feasibility and acceptability, although this is only with regard to female family caregivers.

Furthermore, although not powered for efficacy and despite the lack of comparison group, the reduction in depression and care burden, and the improvement in health-related QOL were shown by the participation of the START-J, from pre-assessment to post-assessment. and anxiety also decreased slightly. Further, these results were mostly maintained at 6-month follow-up, indicating that the effects of the program were sustainable, to some extent, as shown by scores on the PHQ-9, J-ZBI_8, and SF8-MCS. These results are consistent with those of a previous randomized controlled trial by Livingston et al. (2013). Family caregivers of relatives living with dementia might be reluctant to discuss their personal problems with others (e.g., Nandi, 2001). Through participation in START-J and discussing their own caregiving behaviors, it is believed that participants might have the opportunity to resolve their feelings and thoughts by practicing skills such as behavioral analysis, cognitive reconstruction, assertiveness training, behavioral activation, and relaxation. Indeed, this does not mean that they could resolve their problems regarding caring for their relative and be relieved from caregiving; however, the program enabled them to cope well with problems relating to caregiving and to manage the stress of caregiving by acquiring stress management skills.

This small-scale study emphasizes the potential usefulness of START in Japan. This study appears to have clinical importance in that it might increase the number of choices for supporting family caregivers with relatives living with dementia in Japan. The individualized program is time-consuming; however, therapists can respond to diverse family caregivers’ needs and overcome any potential stigma that may prevent family caregivers from speaking in groups. Our future challenge is to see if an individualized program like START-J would be helpful in avoiding any potential stigma, as we were not able to examine the effect of stigma on the participants in this study. Family caregivers are central to Japanese government's plan to establish a society wherein people live with dementia in comfortable and familiar surroundings for as long as possible; thus, family caregivers will need appropriate and effective support for this to be achieved and sustained. START-J can be expected to contribute to this support**.**

Limitations

Financial remuneration may have played a role in participant continuation. We provided the participants with round-trip transportation allowances and rewards for each assessment, which was explained before informed consent was obtained. The original START RCT (Livingston et al., 2013) did not provide any remuneration; thus, we cannot compare this result directly with their work.

In addition, there are two critical differences between this trial and the original START study. First, two clinical psychologists implemented the program in this study, but psychology graduates with no clinical training, although they were trained before the program, delivered the original START study. Second, this trial was conducted in a hospital, not a community setting or a participant's home. This difference in the program delivery may have influenced the results. In particular, the difference in the implementation site could have been related to the paucity of participant candidates, despite that we had over one year to conduct this study.

The more detailed inclusion/exclusion criteria were also different to the original study (Livingston et al., 2013). Our future research requires an investigation into whether we can replicate this result with well-trained, non-professional staff and with the same criteria as the original START study.

This study was designed to consider feasibility and not efficacy. It was a single-arm trial without a control group. Moreover, there were few participants (n = 8) in the trial, with all participating family caregivers being women. In Japan, over 65% of family caregivers with older relatives with/without dementia or MCI are women (Cabinet Office Japan, 2019); male caregivers are far fewer. This could explain the paucity of male candidates for this study. We did not conduct power analysis for evaluating efficacy, as we were evaluating possibilities for implementation in Japan, not efficacy. In addition, the relatives of the participating family caregivers had mixed conditions, MCI, and mild dementia, which required different caring times. For these reasons, the study results may not be generalizable to the overall population and the quantitative data may only be indicative. Therefore, the effectiveness of START-J must be demonstrated through controlled studies with larger groups including both male and female caregivers in the future. Furthermore, this trial was conducted at an outpatient department at an academic hospital, which means that almost all participants were highly motivated to participate in this program. Because of this, we could not avoid and cannot deny selection bias.

Conclusion

The results of this study suggest that, to a limited extent, START-J is a feasible and acceptable tool worth exploring for dementia or MCI care in Japan. This is also supported by the high index of satisfaction observed. Although our data indicate that START-J might have some potential to help reduce depressive symptoms and care burden and improve the overall health-related mental QOL of family caregivers of relatives living with dementia, this was not the purpose of the study. Other psychosocial intervention programs apart from START-J may also be needed to identify effective programs for the caregivers of relatives living with dementia in our super-aged society.

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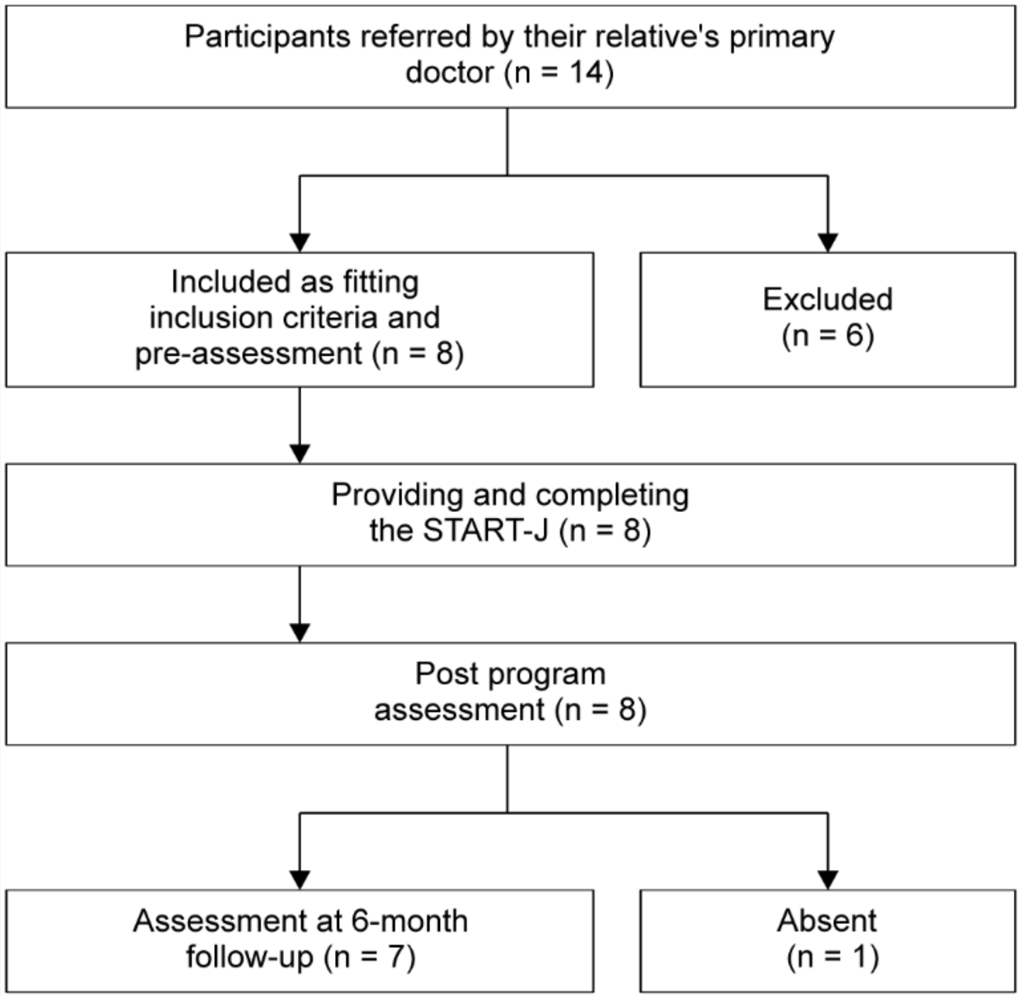
Figure Caption

Figure 1. The flow of participants through the study



Tables

Table 1. Framework of START

Title	Content	Relaxation Training
Session 1: Stress and Well-Being	Psychoeducation and setting a goal.	Signal Breath
Session 2: Reasons for Behavior	Introduction to the "trigger-behavior-reaction chain."	Focused Breathing
Session 3: Making a Behavior Plan	How to manage the relative's problem behaviors.	Physical Grounding
Session 4: Behavior Strategies and Unhelpful Thoughts	Reviewing session 3 and identifying unhelpful thoughts.	Guided Imagery – Meadow and Stream
Session 5: Communication Styles	How to be assertive and express oneself effectively.	Meditation
Session 6: Planning for the Future*	Providing information about care planning.	Guided Imagery – Ocean Escape
Session 7: Introduction to Pleasant Events and Your Mood	Making a plan of pleasant activities for caregivers.	Stretching
Session 8: Using Your Skills in the Future	Reviewing all the sessions.	Guided Imagery – Mountain Cabin

* We revised session 6 because of the differences between the UK and Japanese healthcare systems.

Table 2. Study participants' demographic data (n=8)

Characteristic	Value
Age (years), mean (SD)	62.3 (7.6)
Range	52–71
Gender	
Female, N (%)	8 (100)
Duration of education (years), mean (SD)	12.9 (1.5)
Relationship with relative requiring caregiving	
Wife, N (%)	4 (50)
Daughter, N (%)	4 (50)
Employment status	
Employed, N (%)	5 (63)
Unemployed or retired, N (%)	3 (38)
Marital status	
Married, N (%)	7 (88)
Divorced, N (%)	1 (13)
Relative's diagnosis, N (%)	
Mild cognitive impairment, N (%)	2 (25)
Alzheimer's disease, N (%)	6 (75)
Relative's age (years), mean (SD)	76.5 (9.2)
Range (years)	65 -94
Living arrangements	
Living together, N (%)	6 (75)
Separation: care home, N (%)	2 (25)
Time needed for caregiving (hours per week), mean (SD)	37.0 (31.0)
Range (hours)	10 - 84
Presence or absence of helpmate for caregiving	
Child, N (%)	1 (13)
Parent, N (%)	1 (13)

Aunt, N (%)	1 (13)
Nobody, N (%)	5 (63)
Total	8 (100)

Table 3. Mean scores and standard deviations on the summarized Client Satisfaction Questionnaire-8

	Summarized CSQ-8 item	M (± SD) (n = 8)
1	The quality of service received	3.88 ± 0.35
2	Getting the kind of service wanted	3.88 ± 0.35
3	The extent to which this service met needs	3.88 ± 0.35
4	Recommending this service to a friend	3.88 ± 0.35
5	Satisfaction with the amount of help received	4.00 ± 0.00
6	The service received helped to deal with problems	3.25 ± 0.46
7	Overall satisfaction with the service received	3.63 ± 0.52
8	Wants to come back for this service if need to seek help	3.88 ± 0.35
	total score	30.25 ± 2.25

M: Mean Scores; SD: Standard Deviation

Table 4. Mean scores and standard deviations on all outcomes over the study period

Outcomes	Estimated Marginal Means (±SE)			Pre vs. Post					Pre vs. 6m follow-up				
				mean of difference			Cohen's *d*		mean of difference			Cohen's *d*	
	Pre (n = 8)	Post (n = 8)	6-month (n = 7)	value	95% CI	p-value	value	95% CI	value	95% CI	p-value	value	95% CI
PHQ-9	8.63 ± 1.35	3.38 ± 1.35	3.36 ± 1.42	-5.25	-8.83, -1.67	0.005	1.31	0.22, 2.41	-5.27	-9.00, -1.53	0.007	1.26	0.18, 2.35
HAD-A	4.00 ± 0.76	3.88 ± 0.76	3.25 ± 0.80	-0.13	-2.29, 2.04	1.000	0.05	-0.93, 1.03	-0.75	-3.00, 1.51	0.837	0.29	-0.69, 1.28
J-ZBI_8	14.75 ± 2.00	7.38 ± 2.00	7.25 ± 2.07	-7.38	-11.53, -3.22	0.001	1.59	0.45, 2.74	-7.50	-11.85, -3.15	0.002	1.54	0.41, 2.68
SF8-PCS	44.87 ± 2.04	48.48 ± 2.04	50.39 ± 2.15	3.61	-2.20, 9.42	0.278	0.56	-0.44, 1.56	5.53	-0.51, 11.57	0.075	0.82	-0.21, 1.85
SF8-MCS	40.05 ± 1.73	47.43 ± 1.73	49.11 ± 1.85	7.38	1.61, 13.14	0.013	1.14	0.07, 2.21	9.06	3.10, 15.02	0.004	1.35	0.25, 2.45
NPI-Q	9.25 ± 2.22	5.63 ± 2.22	7.28 ± 2.29	-3.63	-8.04, 0.79	0.116	0.74	-0.28, 1.75	-1.97	-6.59, 2.66	0.602	0.38	-0.61, 1.37
NPI-B	11.25 ± 1.16	6.25 ± 1.16	5.50 ± 2.29	-5.00	-11.73, 1.73	0.166	0.66	-0.35, 1.67	-5.75	-12.73, 1.24	0.116	0.73	-0.29, 1.75

PHQ-9: Patient Health Questionnaire-9, HAD-A: Hospital Anxiety and Depression Scale (Anxiety only), J-ZBI_8: Japanese version of the short version of Zarit Caregiver Burden Interview, SF8-PCS: Short Form 8 Health Survey Questionnaire-Physical Component Summary, SF8-MCS: Short Form 8 Health Survey Questionnaire-Mental Component Summary, NPI-Q: Neuropsychiatric Inventory Questionnaire, NPI-B: Neuropsychiatric Inventory Questionnaire-caregiver's burden.

SE: Standard Error; 95%CI: 95% Confidential Interval